

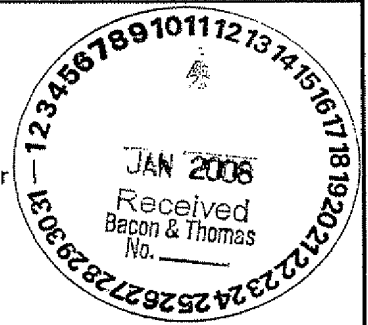
From the INTERNATIONAL BUREAU

PCT**NOTIFICATION CONCERNING
TRANSMITTAL OF COPY OF INTERNATIONAL
PRELIMINARY REPORT ON PATENTABILITY
(CHAPTER I OF THE PATENT COOPERATION
TREATY)**

(PCT Rule 44bis.1(c))

To:

CASELL, Justin, J.
Bacon & Thomas, PLLC
625 Slaters Lane-Fourth Floor
Alexandria, VA 22314-1176
ETATS-UNIS D'AMERIQUE



Date of mailing (day/month/year) 03 January 2008 (03.01.2008)		
Applicant's or agent's file reference GRIM3001PCT(1)		IMPORTANT NOTICE
International application No. PCT/US2006/013863	International filing date (day/month/year) 13 April 2006 (13.04.2006)	
		Priority date (day/month/year) 14 June 2005 (14.06.2005)
Applicant OSSUR HF		

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Dorothee Mülhausen

Facsimile No. +41 22 338 82 70

e-mail: pt01.pct@wipo.int

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference GRIM3001PCT(1)	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2006/013863	International filing date (<i>day/month/year</i>) 13 April 2006 (13.04.2006)	Priority date (<i>day/month/year</i>) 14 June 2005 (14.06.2005)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant OSSUR HF		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 17 December 2007 (17.12.2007)
Facsimile No. +41 22 338 82 70	Authorized officer <div style="text-align: center; font-weight: bold;">Dorothee Mülhausen</div> e-mail: pt01.pct@wipo.int

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: Paul Y. Feng
Fulwider Patton Lee & Utecht, LLP
6060 Center Drive, Tenth Floor
Los Angeles, California 90045

Date of mailing
(day/month/year)

18 SEP 2007

Applicant's or agent's file reference
ROYCE-73526

FOR FURTHER ACTION

See paragraph 2 below

International application No.
PCT/US06/13863

International filing date (day-month year)
13 April 2006

Priority date (day month-year)
14 June 2005

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61F 5/02 (2007.01)
USPC - 602/8

Applicant **ROYCE MEDICAL COMPANY**

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Date of completion of this opinion
05 June 2007

Authorized officer:

Blaine Copenheaver

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US06/13863

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-20	YES
	Claims	NONE	NO
Inventive step (IS)	Claims	NONE	YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims	NONE	NO

2. Citations and explanations:

Claims 1-7 and 9-20 lack an inventive step under PCT Article 33(3) as being obvious over Grim (US 5,437,614) in view of Riedel (US 4,366,814).

Regarding claim 1, Grim discloses a hardenable orthopedic assembly applied to a portion of a patient's anatomy (col. 1, line 67 – col. 2, line 6), comprising a support body of at least one layer of material, the support body being at least partially impregnated with an activatable resin (col. 9, lines 34-47), a primary holding material having an initial unstretched length (col. 3, lines 67-68), and extending laterally from at least one side of the support body (fig. 2), wherein the primary holding material at least partially wraps around the portion of the patient's anatomy (col. 8, lines 17-46). Grim does not disclose wherein a final length of the primary holding material when stretched about 100 % is at least about 30 % longer than the initial length. However, Riedel discloses wherein a final length of the primary holding material when stretched about 100 % is at least about 30 % longer than the initial length (col. 2, lines 46-48). At the time of the invention, it would have been obvious to one skilled in the art to use as a primary holding material a material when stretched about 100 % is at least about 30 % longer than the initial length, as taught by Riedel. The motivation for doing so would have been to avoid the tourniquet effect when the material is stretched.

Regarding claim 2, Grim discloses wherein the support body is at least partially covered by one of a padding and a covering on at least one side (col. 9, lines 34-37).

Regarding claim 3, Grim does not disclose wherein the primary holding material is breathable and porous to ambient air. Riedel discloses wherein the primary holding material is breathable and porous to ambient air (col. 2, lines 12-15). At the time of the invention, it would have been obvious to one skilled in the art to utilize a primary holding material that is breathable and porous to ambient air, as taught by Riedel. The motivation for doing so would have been to enable atmospheric oxygen to interact with skin.

Regarding claim 4, Grim discloses wherein the primary holding material is substantially hydrophobic (col. 3, lines 67-68).

Regarding claim 5, Grim discloses a hardenable orthopedic assembly applied to a portion of a patient's anatomy (col. 1, line 67 – col. 2, line 6), comprising a support body of at least one layer of material that is at least partially impregnated with an activatable resin (col. 9, lines 34-47), a primary holding material disposed on the support body extending laterally from the support body (fig. 2), wherein the primary holding material at least partially wraps around and holds to the portion of the patient's anatomy (col. 8, lines 17-46). Grim does not disclose wherein the primary holding material tears but does not separate when a stretch load L less than or equal to about 44 N and greater than or equal to about 5 N. Riedel discloses wherein the primary holding material tears but does not separate when a stretch load L less than or equal to about 44 N and greater than or equal to about 5 N (col. 3, line 41). At the time of the invention, it would have been obvious to one skilled in the art to use a primary holding material that tears but does not separate when a stretch load L less than or equal to about 44 N and greater than or equal to about 5 N, as taught by Riedel. The motivation for doing so would have been to ensure the stability of the support body while avoiding the tourniquet effect.

Regarding claim 6, Grim discloses wherein the primary holding material includes a section of stretchable material and a section of non-stretchable material (col. 3, line 67 – col. 4, line 1 and col. 4, lines 5-8).

Regarding claim 7, Grim does not disclose wherein the primary holding material initiates a tear but does not separate when a tensile load L less than or equal to about 13.4 N and greater than or equal to about 5 N is applied. Riedel discloses wherein the primary holding material initiates a tear but does not separate when a tensile load L less than or equal to about 13.4 N and greater than or equal to about 5 N is applied (table entitled, "Properties of the New Materials," entry 10).

At the time of the invention, it would have been obvious to one skilled in the art to use a primary holding material that initiates a tear but does not separate when a tensile load L less than or equal to about 13.4 N and greater than or equal to about 5 N is applied, as taught by Riedel. The motivation for doing so would have been to ensure the stability of the support body while avoiding the tourniquet effect.

Regarding claim 9, Grim discloses wherein the support body and the primary holding material include respective complementary areas having means for tacking (col. 8, lines 20-23).

Regarding claim 10, Grim discloses wherein the means for tacking includes an adhesive (col. 2, lines 38-41).

Regarding claim 11, Grim discloses wherein the means for tacking includes hook and loop fasteners (col. 2, lines 38-41).

Regarding claim 12, Grim discloses wherein the means for tacking includes hook fasteners and a UBL material (col. 2, lines 38-41).

Continued in Supplemental Box

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US06/13863

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box V

Regarding claim 13, Grim discloses a hardenable orthopedic assembly applied to a portion of a patient's anatomy (col. 1, line 67 – col. 2, line 6), comprising a support body having opposed ends and opposed sides of at least one layer of material, wherein the support body is at least partially impregnated with an activatable, hardenable resin (col. 9, lines 34-47); a separate primary holding material having an initial unstretched length (col. 3, lines 67-68), and extending laterally from at least one side of the support body (fig. 2), wherein the primary holding material at least partially wraps around the portion of the patient's anatomy (col. 8, lines 17-46). Grim does not disclose wherein the primary holding material can be stretched up to about 30 % of the initial length with a tensile load L of about 4.5 N to about 6.7 N. Riedel discloses wherein the primary holding material can be stretched up to about 30 % of the initial length with a tensile load L of about 4.5 N to about 6.7 N (table entitled, "Properties of the New Materials," entry 15). At the time of the invention, it would have been obvious to one skilled in the art to use a primary holding material that be stretched up to about 30 % of the initial length with a tensile load L of about 4.5 N to about 6.7 N, as taught by Riedel. The motivation for doing so would have been to ensure the stability of the support body while avoiding the tourniquet effect.

Regarding claim 14, Grim discloses wherein the support body is sandwiched in between a covering and padding (col. 9, lines 50-63).

Regarding claim 15, Grim discloses wherein the covering includes a hook receivable material (col. 8, lines 17-20).

Regarding claim 16, Grim does not disclose wherein the primary holding material tears but does not separate when a tensile load L less than or equal to about 13.4 N and greater than or equal to about 5 N is applied. Riedel discloses wherein the primary holding material initiates a tear but does not separate when a tensile load L less than or equal to about 13.4 N and greater than or equal to about 5 N is applied (table entitled, "Properties of the New Materials," entry 10). At the time of the invention, it would have been obvious to one skilled in the art to use a primary holding material that initiates a tear but does not separate when a tensile load L less than or equal to about 13.4 N and greater than or equal to about 5 N is applied, as taught by Riedel. The motivation for doing so would have been to ensure the stability of the support body while avoiding the tourniquet effect.

Regarding claim 17, Grim does not disclose wherein the primary holding material has a width of about 1 inch to about 6 inches. However, Riedel discloses wherein the primary holding material has a width of about 1 inch to about 6 inches (col. 2, lines 19-21). At the time of the invention, it would have been obvious to one skilled in the art to select a primary holding material having a width of about 1 inch to about 6 inches, as taught by Riedel. The motivation for doing so would have been to ensure an adequate recovery force for the primary holding material.

Regarding claim 18, Grim does not disclose wherein the primary holding material can be stretched up to about 30 % of the initial length with a tensile load L of about 4.5 N. Riedel discloses wherein the primary holding material can be stretched up to about 30 % of the initial length with a tensile load L of about 4.5 N (table entitled, "Properties of the New Materials," entry 15). At the time of the invention, it would have been obvious to one skilled in the art to use a primary holding material that be stretched up to about 30 % of the initial length with a tensile load L of about 4.5 N, as taught by Riedel. The motivation for doing so would have been to ensure the stability of the support body while avoiding the tourniquet effect.

Regarding claim 19, Grim does not disclose wherein the support body includes a strip form and can be arranged in a roll. Riedel discloses wherein the support body includes a strip form and can be arranged in a roll (col. 3, lines 39-40). At the time of the invention, it would have been obvious to one skilled in the art to arrange the primary holding material into a roll, as taught by Riedel. The motivation for doing so would have been to manage the storage of the material.

Regarding claim 20, Grim discloses wherein the primary holding material includes opposite ends and each end includes a means for latching (col. 4, lines 5-8).

Claim 8 lacks an inventive step under PCT Article 33(3) as being obvious over Grim (US 5,437,614) in view of Riedel (US 4,366,814), further in view of Klein et al. (US 5,341,513).

Grim discloses wherein the primary holding material includes a shape consisting of an elongated strap form (figs. 1-2). Klein et al. disclose a primary holding material including a shape selected from the group consisting of a polygonal wing form, and a curved wing form (Fig. 2). At the time of the invention, it would have been obvious to one skilled in the art to use a holding material including a shape selected from the group consisting of a polygonal wing form, and a curved wing form, as taught by Klein et al. The motivation for doing so would have been to hold the support body with a tab and slot arrangement.

Claims 1-20 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in the industry.